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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/068,114	02/05/2002	Alain Claude-Marie Daugan	29342/38166	7373

4743 7590 09/24/2003

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EXAMINER

TRUONG, TAMTHOM NGO

ART UNIT PAPER NUMBER

1624

DATE MAILED: 09/24/2003

4

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n N .

10/068,114

Applicant(s)

DAUGAN

Examiner

Tamthom N. Truong

Art Unit

1624

-- The MAILING DATE f this communication appears on th cover sheet with the corresp ndence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 2-5-02 (Prelim Amdt).
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 18-20 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18-20 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☒ Certified copies of the priority documents have been received in Application No. 08/669,389.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>3</u> . | 6) <input type="checkbox"/> Other: |

DETAILED ACTION

Applicant's preliminary amendment of 2-5-02 has been entered. Claims 1-17 have been deleted. Thus, only new claims 18-20 are pending.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

1. **Lack of Description:** Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The claimed method of elevating cGMP by administering the claimed tetracyclic system is not described in the specification. In the specification, formula I has variable R^3 adjacent to the ring carbon having the oxo group ($C=O$) whereas the claimed formula has variable R^2 at the corresponding position. The definition of R^3 includes only hydrogen and C_{1-3} alkyl while the definition of R^2 includes only ring. Thus, the claimed formula is entirely different from that disclosed in the specification, and therefore, it has no support.
2. **Lack of Enablement:** Claims 18-20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which

was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. The generic reaction scheme does not teach a compound of formula I having a ring at the position of R^3 . There is no working example of such a species. Thus, following the guidance provided, one cannot obtain a compound of the claimed formula having a ring at the position of R^3 . As for biological activity, none of the tested compounds has a ring at the position of R^3 . Due to the unpredictable nature of the art, and the structural difference, one cannot extrapolate the biological activity of formula I to the claimed formula, which has a ring at the position of R^3 . Therefore, the claimed method has no enablement in the instant specification.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 18-20 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific asserted utility or a well established utility. Claims 18-20 are directed to “*A method of elevating cGMP levels...*”, and “*A method of potentiating an effect...*” which are not specific to the treatment of any disease.

A revised utility guideline requires that utilities must be specific, substantial, and credible. By specific, said guideline calls for a particular disorder or disease. By substantial, said guideline requires that utilities must define a “real world” use, and must not constitute

further research to identify or reasonably confirm a “real world” context of use. In the instant case, said claims call for *a method of elevating cGMP level*, which is not specific and not substantial as the specification does not appear to relate a particular disorder to said method. The specification lists several “*beneficial*” effects ranging from anti-platelet to the potentiation of 5-HT₁. Then, the specification indicates that the claimed compounds can treat disorders ranging from angina to gastrointestinal (GI) motility. Many of the listed disorders do not share the same etiology. For example, angina and inflammatory diseases (e.g., arthritis) have different pathophysiology. Likewise, bronchitis and glaucoma have different causative factors. Similarly, GI motility does not share the same pathophysiology with other listed diseases. Furthermore, said method is not a well known method to treat many of said diseases, and thus requires extensive further research. Because applicant has not disclosed any specific and substantial utility for the claimed invention, credibility will not be assessed. See *Brenner v. Manson*, 148 USPQ 689, and *In re Zeigler*, 26 USPQ 2d 1600, 1603 (Fed. Cir. 1996).

Claims 18-20 also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

Art Unit: 1624

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 18-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 18 and 19 recite variable R^3 and its definition, which do not have a relationship with the claimed formula. Thus, it is not clear if the claimed formula has R^3 as a substituent or not.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Tamthom N. Truong whose telephone number is 703-305-4485. The examiner can normally be reached on M-F (5:00-12:30) & every Saturday morning (starting from 4-7-03).

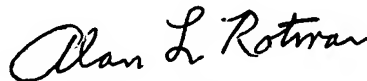
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mukund Shah can be reached on 703-308-4716. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.



T. Truong

September 17, 2003



ALAN L. ROTMAN
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600